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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,802	12/28/2001	Kunal Saha	28335/37036 US	2908

4743 7590 05/30/2003

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EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-56 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-56 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, 29, and 39-55, drawn to gp120 polypeptides, classified in Class 530, subclass 350.

II. Claims 11-23, 30 and 31, drawn to nucleic acid encoding a polypeptide, classified in Class 536, subclass 23.72.

III. Claims 24, 25, and 38, drawn to an antibody, classified in Class 530, subclass 187.1.

IV. Claims 26 and 34, drawn to a method of administering a polypeptide, classified in Class 424, subclass 188.1.

V. Claims 27 and 28, drawn to a method of administering an cells, classified in Class 424, subclass 93.7.

VI. Claim 32, drawn to a method of detecting polypeptides, classified in Class 435, subclass 5.

VII. Claim 33, drawn to a method of detecting nucleic acid, classified in Class 435, subclass 6.

VIII. Claims 35 and 36, drawn to a method of administering an antibody, classified in Class 424, subclass 139.1.

IX. Claim 37, drawn to administering a small molecule, classified in Class 424, subclass 278.1.

X. Claim 56, drawn to a gp41 polypeptide, classified in Class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The compositions of Groups I-III and X are different from the methods of Groups IV-IX because the compositions can be used in materially different methods or can be produced through materially different processes. The compositions are different from each other because the polypeptides of Group I and IX are different peptides and have no common sequence. The compositions are different from each other because they are different chemical compositions with different chemical structures, chemical characteristics, and have no common structure. The searches for each of the compositions would be different and not coextensive.

The methods are each different from the other because they use different starting materials, have different methods steps, and expected results. As above, the searches for each would be different and not coextensive.

The claims of each of Groups I-IX are drawn to multiple sequences. Each of the different sequences are independent and distinct inventions because no common structural or functional properties are shared. Accordingly, these sequences are each subject to restriction under 35 U.S.C. § 121. Regardless of the Group elected, **Applicant is additionally required to elected a**

single sequence, which if determined to be patentable, would also be patentably distinct from other sequences. Examination of more than one sequence in one application would result in an undue burden on the PTO. Failure to elect a specific sequence will be considered to be a non-responsive reply.

Based on an initial review, claims 40-55 appear to be broad recitations covering one or more of the sequences of Group I. Applicant is required to identify which sequence reads on the elected SEQ ID NO. If one or more of claims 40-55 read on more than one SEQ ID NO, that claim or claims will be treated as a linking claim(s) as between those linked sequences only.

A restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant is advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the

instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211; 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability

in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office Action may be made final, or, if the application was already under final rejection, the next Office Action may be an advisory action.

Applicant's attention is hereby directed to the following recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final,

or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


Papers related this application may be submitted to Group 1648 by facsimile transmission. Papers should be faxed to Group 1648 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1648 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PRIMARY EXAMINER